GM FREE CYMRU

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FDA Commissioner Lester Crawford,
Division of Dockets Management (HFA-305),
Food and Drug Administration,
5630 Fishers Lane, Room 1061,
Rockville , MD 20852
USA

5th January 2005

Re: Docket No. 2004D-0369

Dear Commissioner Crawford,

I am writing on behalf of GM Free Cymru to express my deep concern over the FDA's draft "Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use". I am also alarmed that the FDA is intending to promote the FDA guidance as providing "an international model to address the presence of low levels of bioengineered plant material in non-bioengineered crop fields ." For the reasons outlined below, I urge you to withdraw these proposals.

These US proposals to legalize contamination from GM experimental crops are a clear breach of the precautionary approach anchored in the UN agreement dealing with GM crops, the Biosafety Protocol. Taking into account the potential threat of irreversible or serious damage derived from the unknown consequences of introducing untested GM material not intended for human consumption into the food chain, no Government in the world should allow the legalization of experimental GM crops in the food supply.

The implications of these proposals are far-reaching. Not only will they legalise contamination of the US food chain with unapproved, untested GM traits, but food exported to any country in the world will also be at risk. People all over the world have made it clear that they want to be able to choose food free of GM contamination - even if the GMOs are approved by government agencies. But even "approved" GMOs are inadequately understood, and this attempt to legalise food contamination from unapproved GM traits, with unknown consequences,
is reckless and totally unacceptable.

The stated purpose of this guidance document is to set up a voluntary mechanism for evaluating the potential health risks from contamination of the food supply with material from genetically engineered (GE) plants being field tested out-of-doors. However, the true purpose of this initiative has nothing whatsoever to do with food safety. As you have stated in a recent speech, the goals are to "enhance public confidence" and "avoid product recalls" when such contamination occurs. This is both cynical and dangerous. We understand why the Biotechnology
Industry Organization regards the initiative as "enormously important", but it is totally unacceptable for the FDA to protect biotechnology company interests at the expense of consumers. This is not what you are there for.

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In the event that these proposals were approved and US companies subsequently protected from legal liability, significant questions over liability would emerge. For example, who would be liable if contaminated food was exported into, and detected, in other countries in the world? And who would be responsible if negative impacts on human health are discovered in the US or anywhere else in the world as a result of eating food contaminated with experimental GM traits?

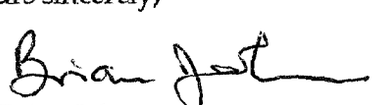
The FDA presumes that any contamination that occurs will be at low levels, lessening concern. Yet "low level" is never defined. Permissible contaminant levels are in principle unlimited. Two considerations suggest that contamination may often be higher than anticipated. First, in some cases the transgenes responsible for novel proteins can cross over to related weed species or compatible cultivars, which can act as a genetic reservoir for the persistence and amplification of the transgene, which could then be transferred back to food cultivars in the future. Secondly, by negating the existing de facto zero tolerance standard for experimental transgenic proteins in the food supply, GE crop field trial operators will have less incentive to strictly adhere to gene confinement protocols, resulting in more, not less, contamination.

Furthermore, the proposed "safety evaluation" is totally inadequate. First, it applies only to experimental GE crop varieties that generate non-pesticidal proteins, by definition excluding the growing number of trials involving metabolic manipulations rather than novel proteins. Secondly, it excludes standard toxicological testing procedures and proposes absolutely no assay to detect unintended effects of the genetic engineering process. Third, experts agree that the digestive stability and amino acid homology tests proposed in the guidance cannot exclude a novel protein's toxicity or allergenicity, particularly since test conditions are not specified, giving applicants ample leeway to devise their own tests to get the results they desire.

I urge you to abandon this misconceived policy. The FDA should be devising rules and procedures to PREVENT contamination of the food supply with experimental transgenic proteins, not to give rubber stamp approval to such contamination when it occurs.

Finally, I urge the FDA to replace its current non-rigorous "voluntary consultation" process with a mandatory, science-based independent review process designed to ensure food SAFETY rather than, as at present, to "enhance public confidence" in inadequately tested and potentially hazardous GE foods.

Yours sincerely,



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